

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include changes to Figure 1-11 and 13-21. These Replacement sheets replace the original sheets of Figures 1-11 and 13-21.

In Figure 1, labeling of the y-axis has been corrected and the title of the figure deleted.

In Figure 2, the title of the figure has been deleted.

In Figure 3, the unit of swelling has been indicated.

In Figure 4, the unit of swelling has been indicated and the legend for the graph corrected to Tp/BCG.

In Figure 5, the unit of swelling has been identified and the legend amended to remove the third line with a solid box.

In Figure 6, the unit of tuberculin response has been identified.

In Figure 7, the unit of swelling has been identified and the legend amended to remove the third line.

In Figures 8-9, the unit of swelling has been identified.

In Figure 10, the unit of swelling has been identified and the y-axis is now correctly typed.

In Figure 11, the typographical error has been corrected.

In Figures 13-20, new figures of better quality have been submitted

In Figure 21, "P," "V" and "T" have been clarified.

No new matter has been added.

REMARKS

Claims 1-3, 12, 14-15, 17-20 and 22 have been amended. New claims 23-26 have been added. Support for the amendments can be found throughout the specification. No new matter has been added. Claims 4-7 and 11 have been cancelled. Applicants reserve the right to prosecute the cancelled subject-matter at a later date.

Clean and marked up copies of a substitute specification are attached. No new matter has been added.

Figures 1-11, 13-20 and 21 have been amended. No new matter has been added.

Claims 1-3, 8-10 and 12-25 are pending

SPECIFICATION

The Examiner has objected to the disclosure due to informalities. For the Examiner's convenience, and due to the nature of the amendments, Applicants provide a clean copy of a substitute specification and a marked up copy of the substitute specification.

Spelling and minor typographical errors have been corrected on page 1, line 30, page 7, line 10, page 11, line 31, page 13, line 30, page 14, lines 1, 18, 20, 27, and 31, page 15, lines 4, 7, 14, 18, and 23, page 19, line 23, page 23, line 14, page 24, line 5, page 26, line 13, page 29, line 10, page 32, lines 2-3, and 13, page 39, line 21, page 40, lines 5, 9, and 19, page 45, line 18, page 46, line 20, page 58, line 21, page 60, line 16, page 64, lines 25, 30, page 65, line 28, page 66, lines 26, and 28, page 67, line 3, page 70, line 11, page 73, lines 7, 10, 16, 17, and 18, page 76, line 23 and page 79, line 18.

With regard to the missing reference (Kay (2001)) and the source missing for the references Sharpe et al., and Manabe et al., Applicants have deleted mention of the Kay, Shapre and Manabe references.

With respect to the objection regarding the missing units for data in Tables 1, 2 and 3 (on pages 52, 55 and 57 respectively) and the Table on page 75, Applicants have amended the Tables to indicate that the tuberculin response is measured in microns. Support for this amendment may be found at, for example, page 65, lines 13-14 and 25. With respect to the Examiner's objection

of Table on page 71, Applicants have amended the Table to indicate that the mean pig weight is measured in kilograms. Support for this amendment may be found at, for example, Figure 11.

Applicants respectfully request the withdrawal of these objections.

DRAWINGS

The Examiner has objected to Figures 1-11, 13-21. See Office Action at p. 4-5. In response to the objections, Applicants submit Replacement Sheets and Annotated Sheets for Figures 1-11 and 13-20. No new matter has been added. The Examiner has further objected to Figure 21 as the Examiner contends that there "is no explanation of 'P,' 'V' or 'T.'" See Office Action at p. 5. With regard to this objection, 'P' refers to buffered saline, 'V' refers to *M. Vaccae* and 'T' refers to *T. inehonesis*. In particular, Example 11 relates to the modulation of stress associated with sweet itch in horses. The specification on page 71, line 25 discloses that groups of ponies and horses known to develop sweet itch received with *T. inehonensis*, *M. vaccae* or buffered saline as a control. The specification on page 72 discloses the results. As can be seen, 'P,' 'V' and 'T' were used to represent the buffered saline, *M. Vaccae*, and *T. inehonesis*. The 'P,' 'V' and 'T' symbols were carried through to Figure 21 and Example 12.

Applicants respectfully request the withdrawal of this objection.

CLAIM REJECTIONS

Rejection under 35 U.S.C. § 101

The Examiner has rejected claims 4-7 under 35 U.S.C. § 101. See Office Action at p. 5-6. In an effort to expedite prosecution and not in acquiescence to the rejection, claims 4-7 have been cancelled thus rendering this rejection moot. Applicants respectfully request the withdrawal of this rejection.

The Examiner has further rejected claims 1-3 and 8-10 under 35 U.S.C. § 101 "because the claimed invention is directed to non-statutory subject matter." See Office Action at p. 6. Specifically the Examiner alleges that "the claims read on a product of nature, i.e., naturally occurring bacteria, alive or dead." *Id.* Applicants respectfully traverse this rejection. Claims 1-3 and 8-10 relate to immune modulator and pharmaceutical compositions that includes 10⁴ to 10¹⁰ killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*,

Nocardia, *Dietzia*, *Tsukamurella* and *Nocardioidea*, and do not read on naturally occurring bacteria. Applicants respectfully request the withdrawal of this rejection with respect to claims 1 and 3 and claims dependent therefrom.

Rejection under 35 U.S.C. § 112

The Examiner has rejected claims 4-7 under 35 U.S.C. § 112, second paragraph. See Office Action at p. 6. In an effort to expedite prosecution and not in acquiescence to the rejection, claims 4-7 have been cancelled thus rendering this rejection moot with respect to those claims. Applicants respectfully request the withdrawal of this rejection.

Rejection under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1-10 under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No 4,599,310 to Matson et al. ("Matson"). See Office Action at p. 7. Claims 1 and 3 are independent claims. Claims 4-7 have been cancelled thus rendering this rejection moot with respect to those claims.

Applicants have discovered an immune modulator composition that includes 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioidea*, wherein said immune modulator composition in use modifies a cellular immune response. See claim 1. Applicants have also discovered a pharmaceutical composition that includes 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioidea* and optionally a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modifies a cellular immune response. See claim 3.

Matson describes an antibiotic (sandramycin) produced by fermentation of a *Nocardioidea* strain. See col. 2, lines 58-60. Matson further describes purifying sandramycin and the uses of this purified antibiotic. See col. 7; line 41 to col. 8, line 64, col. 10, line 62 to col. 12, line 25. Matson does not describe an immune modulator composition that includes 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardioidea*, wherein said immune modulator composition in use modifies a cellular immune response. See claim 1. Matson does not describe a pharmaceutical composition

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that includes 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus*, *Gordonia*, *Dietzia*, *Tsukamurella* and *Nocardoides* and optionally a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modifies a cellular immune response. See claim 3.

Accordingly, independent claims 1 and 3 are not anticipated by Matson. Claims 2-3 and 8-10 depend from claims 1 and 3 and are also not anticipated by Matson for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance. A petition for a one month extension of time is enclosed. The Commissioner is authorized to charge additional claim fees of \$450 to the Deposit Account 19-4293. Should any further fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account 19-4293.

Respectfully submitted,

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